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Indian Standard

SPECIFICATION FOR ELECTRICAL IMPEDANCE PLETHYSMOGRAPH

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Indian Standard
SPECIFICATION FOR ELECTRICAL IMPEDANCE PLETHYSMOGRAPH

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Indian Standard
SPECIFICATION FOR ELECTRICAL IMPEDANCE PLETHYSMOGRAPH

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 23 June 1986, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 This standard covers the safety the performance requirements and test method for single and multi-channel elecrical impedance plethysmograph.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers the safety and performance requirements and test method for single and multi-channel electrical impedance plethysmograph.

2. TERMINOLOGY

2.0 For the purpose of this standard the following definitions shall apply.

2.1 Accuracy — The deviation of a result obtained by a particular method from the true value.

2.2 Electrical Impedance Plethysmograph — Electromedical equipment in which electrodes are directly applied to a patient externally for the purpose of recording the fluctuating voltages caused by the volume or conductivity changes of the segment under study.

NOTE — Electrical impedance plethysmograph is hereinafter referred to as 'plethysmograph' throughout this specification.

2.3 Plethysmogram — Plethysmogram is the record taken with plethysmograph.

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*Rules for rounding off numerical values (*revised*).

2.4 Single Channel Plethysmograph — Equipment for the recording of one plethysmogram only.

2.5 Double Channel Plethysmograph — Equipment for the simultaneous recording or two plethysmograms.

2.6 Linear Distortion — A type of distortion resulting when for a linear change of resistance at the pick up electrode the output does not change linearly.

2.7 Impedance — A measure of the opposition to flow of an alternating current in a circuit caused by the combination of resistance capacitive reactance and inductive reactance. It is the ratio of the effective voltage to the effective current.

2.8 Input Signal — The signal injected into plethysmograph.

2.9 Input Terminals — The terminals for the input signal plethysmograph.

2.10 Noise — Unwanted signals introduced either from the plethysmograph or from other sources.

2.11 Output — The conversion of an input signal as it appears in the form of power, energy or signal from plethysmograph or as it appears in the form of recording at the output terminals.

2.12 Output Terminals — The terminals of the plethysmograph to which external recorder is connected.

2.13 Sensitivity — The ratio of the output potential to input impedance signal.

NOTE — By the above definition, sensitivity should be expressed as mv/mΩ. However, when expressed as mv/mΩ, a higher number will denote higher sensitivity.

2.14 Signal — The impedance changes attributed to volume or conductivity changes of the body segment under study.

2.15 Lead Electrodes — Electrodes fastened to a part of the body to detect volume changes in combination with other electrodes.

2.16 Channel — Comprises input electrodes system, amplifier, demodulator differentiator and filters and output buffer.

3. SERVICE CONDITIONS

3.1 Electrical impedance plethysmograph shall be capable of complying with the requirements of this specification over the full range of each of the following conditions including the combinations thereof :

a) over a temperature range of 0° to 50°C inclusive,

b) at altitudes from sea level to 5 000 m above sea level,

c) at relative humidities from 10 to 95 percent inclusive, and

d) at the following voltages:

   1) for plethysmograph operating from a nominal 240 V, 50 Hz supply at any supply voltage within the range 200-255 volts inclusive and 48-52 Hz inclusive, and

   2) for battery operated plethysmograph to the end point of the voltage limits specified by the manufacturer.

4. CONSTRUCTION AND GENERAL REQUIREMENTS

4.1 All the sub-systems shall be fully solid state.

4.2 The system shall be designed to work from supply mains and/or battery.

4.3 Constant Current Source — Constant current source shall supply a pre-selected rms value of an alternating sinusoidal current through the output terminals.

4.3.1 The operating frequency range from 50 to 100 kHz inclusive. Frequency declared by manufacturer shall remain constant to within ± 5 percent.

4.3.2 Three pre-selected value of rms current (2, 4 and 6 mA) shall be available. The variations allowed in I_0 shall not exceed the rate of 0·001 I_0 per second for small term operation of the system. However, for long term operation, the maximum allowed variation in I_0 shall remain within 5 percent.

4.3.3 The constant current source shall have a transformer isolation from the body.

4.3.4 The electrode cable shall be connected to plethysmograph through a lock-in (5 pin connector with threads for making firm electrical connector) connector.

4.4 Electrodes

4.4.1 The plethysmograph electrodes shall be light weight and comfortable for the patient to wear.

4.4.2 The electrodes shall be of 8 to 10 mm width and shall be such as to provide proper contact with the body.

4.4.3 The electrodes shall be made of suitable non-corrodible material.

4.4.4 The electrode cable shall be connected to the plethysmograph through a suitable plug.

4.5 Controls and Functions — The following controls and functions shall be available on the panel of the systems.

4.5.1 Power ON, OFF switch, with an 'ON' indication.

4.5.2 Selection switch for the operation of the system in calibration mode (CAL) or patient mode (PAT).

4.5.3 Electrode Connector — The patient cable shall be connected through this connector.

4.5.4 Current selection switch for selection of I_0 shall be provided.

4.5.5 Digital panel meter for displaying the impedance up to one decimal place in ohms.

4.5.6 Output terminals connectors for ΔZ and dZ/dt output, to be connected to a strip chart recorder.

4.5.7 Gain control for controlling the gain of the buffer amplifier.

5. SAFETY AND PERFORMANCE REQUIREMENTS

5.1 Compliance with Other Requirements — The electrical impedance plethysmograph shall comply with the relevant requirements specified in all the parts of IS : 8607*.

5.2 Isolation from Supply Mains — (Mains operated electrical impedance plethysmograph only).

5.2.1 Plethysmograph operating from the mains supply shall have all patient circuits effectively isolated from the mains supply by means of a transformer having the secondary winding insulated from the primary winding.

NOTE — Separate bobbins for primary and secondary windings are a suitable means for ensuring adequate separation between such windings.

Conductors and components electrically connected to the patient circuit shall be:

a) double insulated from; and

b) arranged and supported so that in the event of such as loosening of terminals due to breaking of conductors they can not make electrical contact with live conductors and components electrically connected to the primary winding of the transformer.

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*General and safety requirements for electrical equipment used in medical practice.

5.3 Cord Anchorages — The relevant requirements specified in IS : 302-1979* shall apply.

5.4 Screw, Threads and Fixing — The relevant requirements specified in IS : 302-1979* shall apply.

6. TESTS

6.0 The plethysmograph shall satisfactorily pass the test prescribed in the following clauses, such tests being performed in the order in which they appear in Table 1.

Unless otherwise specified the general test conditions shall comply with these specified in IS : 8607 (Part 1)-1977†.

6.1 Type Tests — The tests specified in Table 1 shall constitute type tests. These tests shall be carried out on a number of samples of the plethysmograph of same model, type and ratings selected preferably at random from a regular production lot.

6.1.1 All samples shall successfully pass all the type tests for proving conformity with the requirements of this standard. If any of the samples fails in any of the type tests, the testing authority at its discretion may call for fresh sample not exceeding twice the original number and subject them to all the tests or the tests in which failure(s) occurred. No single failure shall be permitted in the repeat tests.

TABLE 1 TYPE TESTS

(*Clauses* 6.0 *and* 6.1)

SL No.	TEST	CLAUSE REFERENCE
(i)	Insulation resistance	6.3
(ii)	High voltage	6.4
(iii)	Moisture resistance	6.5
(iv)	Cord anchorage	5.3
(v)	Screws, threads and fixing	5.4
(vi)	Output	6.6
(vii)	Leakage current	6.7

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*General and safety requirements for household and similar electrical appliances (*fifth revision*).

†General and safety requirements for electrical equipment used in medical practice: Part 1 General.

6.2 Routine Tests — The tests specified in Table 2 shall constitute routine test and these tests shall be carried out on each and every unit.

TABLE 2 ROUTINE TESTS

SL No.	TESTS	CLAUSE REFERENCE
(i)	Insulation Resistance	6.3
(ii)	Output	6.6
(iii)	Leakage current	6.7

6.3 Insulation Resistance Test — The insulation resistance shall be measured at a voltage of 500 volts between:

a) live supply terminals, and any exposed conductive parts and/or metal foil placed in intimate contact with non-conductive parts liable to be handled in service;

b) live supply terminals, and all patients electrodes connected together;

c) the parts of the double insulated transformer listed in column 1 of Table 3.

6.4 High Voltage Test — Impedance plethysmograph shall be subjected to an ac voltage of:

a) 1 000 V rms applied between the parts specified in **6.3** (a);

b) 1 000 volts rms applied between the parts specified in **6.3** (b), the patient electrodes being connected to earth;

c) the voltage specified in col 3 of Table 3 applied between the corresponding parts specified in col 1 of Table 3.

The voltage shall be applied in accordance with the relevant requirements of the high voltage test in IS : 302-1979*.

There shall be no failure or arcing over the insulation during any of the tests, and immediately following the tests, the insulation resistance test described in **6.3** shall be repeated. The insulation resistance so measured shall comply with the requirements of **6.3**.

6.5 Moisture Resistance — Plethysmograph shall be subjected to and shall comply with the humidity test described in IS : 302-1979* except that high voltage test required therein shall be replaced by that specified in **6.4**.

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*General and safety requirements for household and similar electrical appliances (*fifth revision*).

TABLE 3 INSULATION RESISTANCE AND HIGH VOLTAGE TEST VALUES FOR DOUBLE INSULATED TRANSFORMER

(*Clause* 6.3)

PARTS (1)	INSULATION RESISTANCE (2) MΩ	HIGH VOLTAGE TEST VALUES (3) kV (rms)
Between input and output winding	100	3.5
Between the input winding and core connected to any screw or any exposed conductive parts	10	1
Between the output winding and core connected to any screw and any exposed conductive parts	10	1

6.6 Output Test

6.6.1 Calibration 24·7 to 25·3 ohms should be displayed as the impedance of built in calibration resistance (25 ± 1 percent). A triangular and a rectangular wave-form of frequency 1 Hz, and amplitude 0·25 and 1·0 V shall be available as ΔZ and dZ/dt output respectively.

6.6.2 *Range* — The instrument shall be able to measure any impedance from 10-100 ohms with an accuracy of 1 percent.

6.7 Leakage Current

6.7.1 *Leakage Current between Mains Supply and External Parts* — The equipment shall be connected in the manner shown in Fig. 1 where by the active and neutral supply conductors can be transpored. Any earthing conductors to the equipment shall be disconnected and the equipment shall be mounted so as to be isolated from earth. The neutral conductor of the test circuit shall be connected to earth. The equipment shall be operated until maximum operating temperature is reached.

The leakage current shall be measured with the conductors connected normally and than with the supply conductors reversed. When taking each measurement the controls of the equipment shall be adjusted over the completed range liable to be used in normal practice.

The leakage current shall be measured with the conductors connected normally and then with the supply conductors reversed. When taking each measurement the controls of the equipment shall be adjusted over the complete range liable to be used in normal practice.

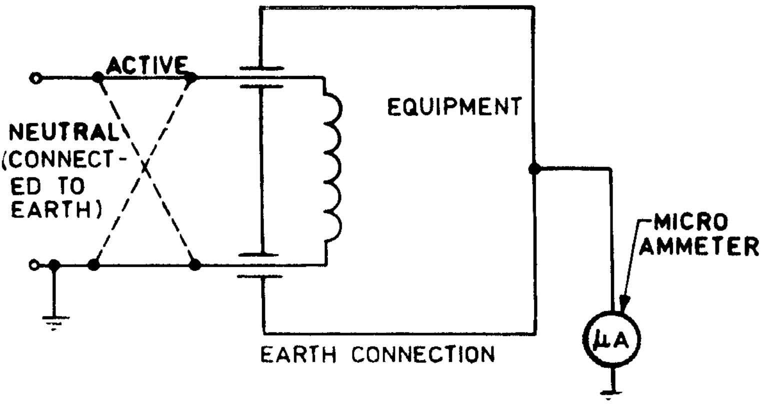

FIG. 1 SCHEMATIC DIAGRAM FOR TESTING LEAKAGE CURRENT BETWEEN MAINS SUPPLY AND EXTERNAL PARTS

The leakage current shall be measured between earth and external metal parts of the plethysmograph or metal foil arranged in intimate contact with external insulating parts. Measurement shall be made with an instrument capable of clearly indicating 100 μA instantaneous. The leakage current so measured shall not exceed an instantaneous value of 100 μA.

6.7.2 *Leakage Current between Mains Supply and Patient Circuits* — The equipment shall be connected in the manner shown in Fig. 2 whereby the active and neutral supply conductors can be transposed, and all patient electrodes are connected together and to the earth pin of the mains connecting plug. Any earthing conductors to the equipment shall remain connected but the equipment shall be mounted so that its case is isolated from earth. The equipment shall be mounted so that its case is isolated from earth. The equipment shall be operated until maximum operating temperature is reached.

The leakage current shall be measured in each patient electrode in turn with the active and neutral supply conductors connected normally and then with such supply conductors reversed. When taking each measurement, the controls of the equipment shall be adjusted over the complete range liable to be used in normal practice.

Measurement shall be made with an instrument capable of clearly indicating continuous alternating and transient current of 10μA for (a) below and 100μA for milli-seconds for (b) below. The instrument shall have a resistance of 1 kohm or be connected in series with a suitable resistor, such that the combined resistance of instrument and resistor is 1 kohm.

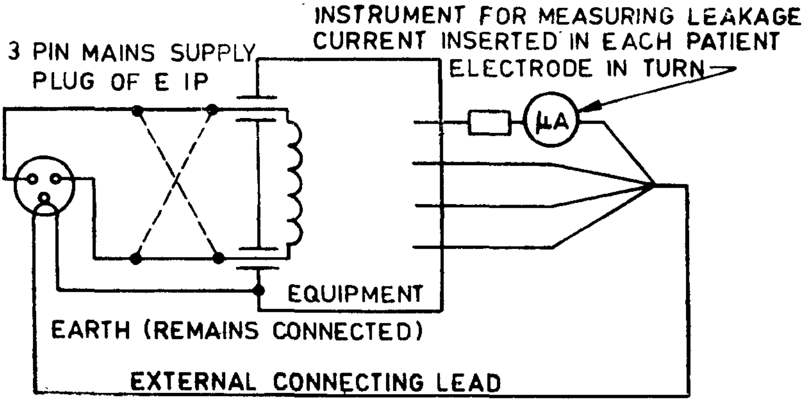
INSTRUMENT FOR MEASURING LEAKAGE CURRENT INSERTED IN EACH PATIENT ELECTRODE IN TURN
3 PIN MAINS SUPPLY PLUG OF E IP
μA
EQUIPMENT
EARTH (REMAINS CONNECTED)
EXTERNAL CONNECTING LEAD

FIG. 2 SCHEMATIC DIAGRAM FOR TESTING LEAKAGE CURRENT BETWEEN MAINS SUPPLY AND PATIENTS CIRCUITS

The leakage current so measured in each electrode shall:

a) not exceed an instantaneous value of 100μA with all controls set and maintained at any position;

b) have a magnitude not exceeding 100μA peak, and a duration not exceeding 5 milliseconds in the case of transient currents caused by any manipulations of the plethysmograph (for example, adjusting of switch or controls, connection or disconnection of plugs and sockets).

INDIAN STANDARDS
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ELECTROMEDICAL EQUIPMENT

IS:

1885	Electrotechnical vocabulary:
(Part 43)-1977	Electrical equipment used in medical practice
(Part 61)-1985	Terminology for nuclear medical instruments
2032 (Part 19)-1977	Graphical symbols used in electrotechnology: Part 19 Electrical equipment used in medical practice
6991-1985	Radiographic cassettes (*first revision*)
7064-1973	Radiation protection in medical X-ray equipment operating at 10 kV to 400 kV
7583-1974	Radio frequency diathermy apparatus
7620-1986	Diagnostic medical X-ray equipment: Part 1 General and Safety requirements (*first revision*)
7620 (Part 2)-1986	Diagnostic medical X-ray equipment: Part 2 Performance requirements (*first revision*)
8048-1976	Electrocardiograph
8607	General and safety requirements for electrical equipment used in medical practice:
(Part 1)-1977	General
(Part 2)-1978	Protection against electric shock
(Part 3)-1979	Protection against mechanical hazards
(Part 4)-1985	Protection against unwanted or excessive radiation
(Part 5)-1983	Protection against explosive hazards
(Part 6)-1984	Protection against excessive temperature rise and other hazards
(Part 7)-1985	Construction
(Part 8)-1985	Behaviour and reliability
8885-1978	Electromyograph
8902-1978	Area exposure product meter
9286-1979	Cardiac defibrillators
10550-1983	Medical treatment lamps
10554-1983	Radiographic intensifying screens for medical use dimensions
11302 (Part 1)-1985	Electro encephalograph: Part 1 General and safety requirements
11302 (Part 2)-1985	Electro encephalograph: Part 2 Particular requirements for performance
11331-1985	Electrical muscle and nerve stimulator for therapeutic purpose
11393-1985	Scintillation counters
11478 (Part 1)-1985	Application guide for medical equipment: Part 1 General requirements and electrical installation
11478 (Part 2)-1985	Application guide for medical equipment: Part 2 Safety provisions, application, operation and maintenance.